1.0 Purpose:

The purpose of this policy is to describe Division of Microbiology and Infectious Diseases (DMID) requirements and processes for document translation by clinical research sites/award institutions.

- All translated essential documents, and other research-related materials presented to study participants, clearly and accurately
  - reflect the proposed study, including procedures, risks, possible benefits, and participant expectations.
  - describe protections for ensuring the safety of study participants and the integrity of the data throughout the course of the clinical research.
- Review and approval of documents by local authorities and Institutional Review Board(s)(IRB) / International Ethics Committee(s) (IEC) must ensure content consistent with the approved protocol and comply with U.S. Code of Federal Regulations 45 CFR 46, (and 21 CRF 50 if under IND), International Conference on Harmonization (ICH E6) Good Clinical Practice (GCP), and applicable country, state or regional requirements.
- All documents required for review by DMID must be translated in English.

2.0 Scope:

To whom this policy applies:

2.1 Division of Microbiology and Infectious Diseases (DMID) staff responsible for the oversight of DMID-supported clinical research.

2.2 Principal Investigators and their staff conducting DMID-supported clinical research are responsible for document translation (see section 6.1, and 6.2).

3.0 Background:

The Division of Microbiology and Infectious Diseases (DMID) supports, through both the contract and grant mechanisms, a large number of clinical studies and trials at non-U.S. locations. DMID also supports clinical research in U.S. sites where non-English speaking participants are recruited and enrolled for clinical research studies. Because DMID clinical research is conducted in various settings, a policy on translation of research-related documents and materials has been developed.

To meet the requirements of 45 CFR 46 and 21 CFR 50, or international equivalencies, the informed consent document should be in language understandable to the subject (or authorized representative). Refer to FDA Information Sheet on Non-English speaking subjects for guidance on non-English speaking and illiterate subjects.

In addition, research-related documents and materials used at clinical research sites by non-English speaking participants, and/or non-English speaking staff must be in a language they understand. Specific document requirements are delineated in the *DMID Language and Translation Summary* document.

4.0 Definitions:

Essential documents - As defined by ICH Guidance Section 1.23, documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced (see Section 8. *Essential Documents for the Conduct of a Clinical Trial*).

5.0 Responsibilities:

Role	Responsibilities
Translator	-Translates identified documents and attests to the accuracy and completeness of the translation. - Provides original and translated documents to the verifier, when translator is also the author of the document. -Completes DMID Translation Equivalence Form to document initial translation.
Verifier* *Verifier is required to attest the accuracy and completeness of the translation *when the author and translator are the same person.*	--Verifies the translation of identified documents and documents any discrepancies. -Completes the DMID Equivalence Form to verify the translation
Principal Investigator	-Responsible for the equivalency of all documents translated as documented by signature on the DMID Equivalence Form
DMID Branches/Offices	-Informs the clinical sites of required documents to be translated. -Reviews translated documents against applicable federal regulations. -Approves / provides recommendations for translated documents prior to the site submitting to their respective IRB/IEC.
Clinical Research Site/Award Institution	- Initiates translation process (see Translator, Verifier) - Verifies site resources/staff available to provide language support to research participants throughout the course of the study.

6.0 Implementation

6.1 Document Translation Process Overview:

6.1.1 The consent document and volunteer information must be in a language understood by the volunteers/participants and approved by the awarded institution's IRB/IEC..

6.1.2 In order to effectively communicate accurate and complete research-related information to study participants throughout the course of the study, clinical

research sites must assure there is available staff who speak the translated language or dialect, and can facilitate participant understanding of the research procedures..

6.1.3 The clinical research site's institution is responsible for initiating the translation process for all research-related and essential documents, obtaining approval from DMID prior to IRB/IEC approval(s), providing follow-up translations for amended documents.

6.1.4 Requirements and instructions for translation are summarized in the following forms:

6.1.4.1 *DMID Translation Equivalence Form (Appendix A)*. This form identifies the translator, lists the documents translated, documents the review process, and includes an attestation by the Principal Investigator that the translation is accurate and complete. This form is used for each protocol-related document to be translated The *Protocol Site Information* section must be completed for <u>each</u> form submitted. A *new DMID Translation Equivalence Form must be completed and submitted each time a document is amended.*

6.1.4.2 *DMID Language and Translation Requirements Summary (Appendix B).* This table summarizes the requirements for translation for essential documents.

6.2 Document Translation Process – Clinical Sites/Award Institution

6.2.1 For non-U.S sites, DMID requires a back-translation if the consent and participant information were originally written in English and reviewed by DMID. Back-translation must not be performed by the original author or translator.

6.2.2 For U.S sites administering the consent and participant information in both English and non-English languages, a back-translation will not be required, but the *DMID Translation Equivalence Form* must be submitted to DMID.

6.2.3 Other entities, with whom the award institution interacts, may have more stringent requirements.

6.2.3.1 The institution receiving the award is responsible for obtaining approval from their institution, as well as approval from any local IRB / IEC for the clinical research sites, and submitting the approval(s) to DMID.

6.2.3.2 All essential documents, SAE forms and supportive safety documentation created at the clinical research site must be translated into English when submitted to DMID.

6.3 Document Translation Process – Review and Approval by DMID:

6.3.1 DMID Branches/Offices/or designee reviews translated documents and provides approval prior to the clinical site submitting those documents to the respective

IRB/IEC. This process ensures the documents meet applicable federal regulations for human subjects protections; and, where applicable, requirements for submission to the U.S. Food and Drug Administration (FDA), if the study is filed under IND.

7.0 References:

7.1 Appendix A: DMID Translation Equivalence Form
7.2 Appendix B: DMID Language and Translations Requirements Summary
7.3 DMID Clinical Trials Management Resources (Password-protected: Translated DMID Source Documentation Standards and Regulatory File Guidelines in French, Portuguese and Spanish; ICH translated in Spanish)
7.4 DMID Source Document Standards
7.5 DMID Regulatory File Document Guidelines
7.6 FDA Information Sheet on Non-English speaking Subjects
7.7 Federal Register: Clarification of HHS' Position (HHS conducted or supported research)
7.8 Council for International Organizations of Medical Sciences (CIOMS) - International Ethical Guidelines for Biomedical Research Involving Human Subject
7.9 Office of Human Research Protections – International Issues

8.0 Inquiries:

Inquires related to this document can be submitted to;

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9.0 Availability:

This document is available electronically:

DMID Internet: http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/protdev.htm
http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/policies.htm

DMID Intranet: (password protected)

DMID Clinical Trials Management: Protocol and Concept Development (password-protected)
https://www.dmidctm.com/partners/SectionProtocolConceptDevelopment/PageProtocolTemplates/ProtocolTemplates.htm

10.0 Change Summary:

Version number	Date of Revision: DD/MMM/YYYY	Replaces	Effective Date: DD/MMM/YYYY	Description of Revision/Retirement	Revisions Initiated by
1.0	N/A	N/A	27-Nov-2007	N/A	
2.0	10-Nov-2008	Version 1.0	15-Dec-2008	Annual review	DMID Policy Development Core Team